UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

BARBARA GAYLE, *et al.*,	)	
	)	
Plaintiffs,	)	Case No. 1:19-CV-03451-WHP
	)	
v.	)	
	)	
PFIZER INC., *et al.*	)	
	)	
Defendants.	)	

PFIZER INC.'S SUPPLEMENT TO MOTION FOR JUDGMENT ON THE PLEADINGS

Pursuant to the Court's bench order during the December 13, 2019 hearing on Pfizer Inc.'s ("Pfizer") Motion for Judgment on the Pleadings, Pfizer submits the FDA's Approval Package for Lipitor accompanying the February 2012 label change for Lipitor, attached as **Exhibit A**. The Approval Package is a judicially noticeable document available on the FDA's website and may be considered at the judgment-on-the-pleadings stage.[1] The Approval Package contains the FDA's Medical Review, in which the FDA states that the near-class-wide label change relating to "[i]ncreases in HbA1c and fasting plasma glucose" was prompted by a study showing an "increase in investigator-reported diabetes mellitus in rosuvastatin-exposed subjects compared to placebo-exposed subjects," discusses the purported "effect of statins on incident diabetes, and increases in HbA1c and/or fasting plasma glucose," and identifies literature that it considered. Ex. A at pp. 18-19 of FDA Medical Review (or pp. 77-78 of PDF).

As set forth in Pfizer's briefing in support of its Motion, the change that the FDA directed Pfizer to make to the Lipitor label as a result of this review demonstrates that the FDA considered

[1] FDA labeling and public announcements are judicially noticeable public documents the authenticity and contents of which are not reasonably subject to dispute. *See In re Restasis (Cyclosporine Ophthalmic Emulsion) Antitrust Litig.*, 333 F. Supp. 3d 135, 152 (E.D.N.Y. 2018); *Gross v. Stryker Corp.*, 858 F. Supp. 2d 466, 481 n.26 (W.D. Pa. 2012); *Lewkut*, 724 F. Supp. 2d at 653 (S.D.N.Y. 2010); *Trisvan v. Heyman*, 305 F. Supp. 3d 381, 400 (E.D.N.Y. 2018).

whether to add a warning that Lipitor increases the risk of diabetes. The Medical Review confirms that the FDA determined that the evidence did not support a warning that Lipitor causes diabetes, but rather the following warning, which remains in the Lipitor label: "Increases in HbA1c and fasting serum glucose levels have been reported with HMG-CoA reductase inhibitors." As explained in Pfizer's Motion and Reply, Plaintiffs have not identified any newly acquired information—information showing a different or more frequent risk—that would have allowed Pfizer to include a different warning pursuant to the CBE regulation. Accordingly, Plaintiffs' claims arising after February 2012 are preempted.

Dated: New York, New York
December 16, 2019

Respectfully submitted,

/s/ Mark Cheffo

Mark Cheffo
Rachel Passaretti-Wu
Mara Cusker Gonzalez
Lincoln Wilson
DECHERT LLP
Three Bryant Park
1095 Avenue of the Americas
New York, NY 10036-6797
Tel: 212-698-3500
Fax: 212-698-3599
mark.cheffo@dechert.com
rachel.passaretti-wu@dechert.com
maracusker.gonzalez@dechert.com
lincoln.wilson@dechert.com

Attorneys for Defendant Pfizer Inc.

CERTIFICATE OF SERVICE

I hereby certify that on December 16, 2019, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system, which sends electronic notification of such filings to all CM/ECF participants.

/s/ Mark Cheffo
Mark Cheffo